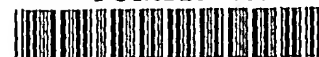


Translation

PATENT COOPERATION TREATY

PCT/JP2004/005547



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5063-PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/005547	International filing date (day/month/year) 19 April 2004 (19.04.2004)	Priority date (day/month/year) 23 April 2003 (23.04.2003)
International Patent Classification (IPC) or national classification and IPC A61J 1/05		
Applicant OTSUKA PHARMACEUTICAL FACTORY, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 20 July 2004 (20.07.2004)	Date of completion of this report 23 March 2005 (23.03.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/005547

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/005547

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-18	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

Document 1: JP, 2002-68963, A (Rohto Pharmaceutical Co., Ltd.), March 8, 2002 (03.08.02), Full text, in particular, paragraphs 0054 and 0061, all drawings (Family: none)

Document 2: JP, 8-34422, A (Taisho Pharmaceutical Co., Ltd.), February 6, 1996 (02.06.96), Full text, all drawings (Family: none)

Document 3: JP, 60-24844, A (Naigai Kasei K.K.), February 7, 1985 (02.07.85), Full text, all drawings (Family: none)

The inventions relating to claims 1, 6 and 13 do not appear to involve an inventive step based on documents 1 and 2 cited in the international search. Document 1 (paragraph 0054) describes producing an inner layer from a hard synthetic resin with a property of preventing adsorption and an outer layer from a laminated body of a soft synthetic resin. An example of Fig. 4 in particular describes a fusion bonded part. Document 2 (paragraphs 0002 through 0004) describes a production method. Configuring this parison in a multilayer structure could be easily conceived of by a party skilled in the art.

The inventions relating to claims 2-5 and 7-12 do not appear to involve an inventive step based on documents 1 and 2, and document 3, which is cited in the international search and disclosed in the specification by the applicant. Document 3 describes various functional layers.

The inventions relating to claims 13-18 do not appear to involve an inventive step based on documents 1-3. An annular polyolefin resin is well known as a medical container material.

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.

**PCT/JP2004/005547**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The specification (page 2, lines 11-17) describes, as a problem of prior art, that a multilayer structure may be broken when sealed by a heat seal. However, why this problem can be avoided by the method in claim 13 of the present application, namely, "a mouth part of a container main body is inserted in an upper split mold, a fusion bonded part for sealing the mouth part ... molded" does not make sense.